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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,720	11/25/2003	Antonia C. Kaloidis	820.001USU	5764

7590 10/04/2007  
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EXAMINER
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WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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10/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/721,720

Applicant(s)

KALOIDIS, ANTONIA C.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 9-26 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-7 and 9-26 are pending. Claim 8 has been canceled.

#### ***Response to Amendment***

The amendments filed September 18, 2006 and January 4, 2007, have not been entered because they were non-responsive and/or non-compliant for reasons of record. However, the amendment filed March 6, 2007, has been entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on May 24, 2004, was filed and received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-12, in the reply filed on April 24, 2006, is acknowledged.

Claims 13-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 24, 2006.

#### ***Specification***

The specification is objected to for the recitation of "cellulose" at page 10, line 15, which appears to be a misspelling like it was in the claims. Appropriate correction is

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required for the specification at each place wherein it is appropriate for said correction in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 9 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims present new matter with respect to the term "flavanones" wherein the instant disclosure does not have original support for this compound. Applicants, therefore, do not have possession of these claims at the time the claimed invention was made and filed before the office. Unless Applicants can demonstrate that they do indeed have possession at the time the claimed invention was made of these compounds as claimed for use in the claimed method these claims are deemed new matter. There is no support for this compound in the specification or at least none could be noted by the Examiner. The term should be removed from these claims or appropriate support for the term should be pointed out to the Examiner by referring her to the specification at page and line number wherein support is noted to define and teach "flavanones".

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is rendered vague and indefinite for the recitation of the term "physiologically acceptable amount" of bacteria because it is unclear what amount would constitute a "physiologically acceptable amount", per se. The metes and bounds of the claim is unclear.

***Claim Rejections - 35 USC § 103***

Claims 1-7, 9-12 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al in view of Izvekova et al (US 6156320) and Wu (US 5595743), and **newly cited** Pandol et al---(Pandol et al cited on an enclosed PTO-892 Form).

Claims are drawn to method for treating spinal muscular atrophy (SMA) comprising administering vitamin C, flavenoid and pectin and optionally a carrier (i.e. water, dispersion). Also claims are further drawn to a method of treating SMA comprising administering vitamin C and apple pectin or pomace pectin or citrus pectin or Lactobacillus acidophilus, or supplemental enzyme such as amylase.

Li et al teach method for treating spinal muscular atrophy (SMA) comprising administering vitamin C and phenol and optionally a carrier (i.e. water, dispersion).

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Note the title and column 5, lines 49-50 and 59. Further, note at column 6, wherein orange flavoring is disclosed.

Izvekova et al teach fermented nutraceuticals for treating atrophy comprising administering *Lactobacillus acidophilus* and apple pectin, vitamin C, etc. Note column 4, lines 44-45, and lines 57, 58 and see the abstract. Also note at column 5, lines 36 and 64-65 that the nutraceuticals are used for treating atrophy, etc.

Wu teaches medicinal treatment that includes supplemental enzyme, such as amylase, note the abstract.

Pandol et al teach polyphenolics are flavenoids, note column 3, lines 10-11 and 50. The disclosed Pandol et al composition comprises an inhibitor, polyphenolic compound (i.e. flavenoid) and carrier, column 4, lines 20-25.

The claims differ from Li et al in that polyphenols, *Lactobacillus acidophilus* and apple pectin as well as supplemental enzyme such as amylase are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine with Li et al the polyphenolics of Pandol et al and *Lactobacillus acidophilus* and apple pectin of Izvekova et al and supplemental enzymes of Wu in order to provide for effective treatment of SMA. Pectins, including apple pectin are clearly disclosed to be useful for treating atrophy, note Izvekova as discussed above. Also many flavenoids are disclosed by Pandol et al. Thus, to select for another flavenoid (i.e. flavenols or those such as citrus flavenoid) and/or citrus pectin, is clearly within the purview of an ordinary artisan and an obvious modification of the cited prior art. Also *Lactobacillus* is clearly an enteric bacterium and disclosed by

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the cited prior art. Further the enzyme is disclosed as is the selection of water as a liquid carrier ingredient.

Therefore, these other ingredients are well recognized in the cited prior art for treating effects of atrophy from diseases such as SMA and would have been expected to provide successful results because Pandol et al disclose flavenoids (i.e. polyphenols) in direct combination with inhibitors. Li et al teach combining inhibitor with vitamin C phenol, and carrier, therefore, one of skill would have expected successful results for the selection of flavonoids. Further, one of skill would have been motivated to add these ingredients to increase effective treatment of atrophy resulting from SMA because Li et al and Izvekova et al clearly teach the main ingredients for treating atrophy. Clearly one of skill would have desired to improve a treatment protocol by adding well known ingredients in combination to with the expectation of successful results. The claims are *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments filed June 27, 2006, have been fully considered but they are not persuasive. The amendments and arguments addressing the 102/103 rejection over Li et al alone are deemed persuasive. However, the amendments have prompted a new rejection. The arguments addressing the straight 103 rejection of record are noted. As set forth above the newly cited Pandol et al reference clearly teach polyphenolics of which are comprised of phenols and the new teaching in combination with Li et al clearly suggest treating SMA with flavenoids. In response to applicant's arguments against the references individually, one cannot show nonobviousness by

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attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, the arguments addressing a gap are deemed moot by the new rejection and because Pandol et al clearly close the gap because they clearly do teach, or at least suggest, the combination of inhibitors as disclosed by Li et al with flavenoids, and Li et al do further teach vitamin C and Izvekova et al teach pectin. Each of the cited references do teach the claimed ingredients and one of skill would have been motivated to combine them with the composition of Li et al for treating SMA because SMA is well recognized to be treatable with inhibitors and vitamin C and phenols which do suggest using flavenoids as discussed above. Pectins and flavenoids are clearly disclosed and are taught or at least are suggested to be capable of treating atrophy (i.e. SMA). The claims are rendered prima facie obvious over the newly applied art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKW

Deborah K. Ware  
September 28, 2007



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128/1657